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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,785	03/30/2004	Nathan D. Cahill	86560SLP	4219
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Carestream Health, Inc. 150 Verona Street Rochester, NY 14608			EXAMINER AZARIAN, SEYED H	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/812,785	Applicant(s) CAHILL ET AL.	
	Examiner Seyed Azarian	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/22/05&3/30/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. Claim 10 is rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. The Federal Circuit, relying upon Supreme Court precedent, has indicated that a statutory “process” under 35 U.S.C. 101 must (1) be tied to a particular machine or apparatus, or (2) transform a particular article to a different state or thing. This is referred to as the “machine or transformation test”, whereby the recitation of a particular machine or transformation of an article must be impose meaningful limits on the claim’s scope to impart patent-eligibility (See *Benson*, 409 U.S. at 71-72), and the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity (See *Flook*, 437 U.S. at 590”). For example claim 10, “A method for identifying anatomical structure depicted in an in vivo image, comprising the steps of a”. While the claims recite a series of steps or acts to be performed, the instant claims neither transform underlying subject matter nor positively tie to particular machine that accomplishes the claimed method steps. In order for process to be “tied” to a particular machine, the structure of a particular machine should be positively recited in a step or steps significant to the basic inventive concept, and not just in association with statements of intended use or purpose, insignificant per or post solution activity, or implicitly. Appropriate correction is required. In re *Bilski* 88 USPQ2d 1385 (Fed. Cir. 2008).

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.3218 may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 10, 19 and 25 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, of U.S. Patent No. 7,319,781. Each of the limitation set forth in the claims of the instant application is defined in the claims of the patent.

As an example consider claim 1, of current application, compared to claim 1, of patent application, it disclose: A digital image processing method for aligning in vivo image from multiple passes of a gastrointestinal tract to aid in diagnosing gastrointestinal disease, comprising the steps of: a) conducting multiple passes of in vivo imaging within the gastrointestinal tract; b) forming a registration bundle of metadata for each of the multiple passes; c) identifying features of an in vivo image using digital image processing that enable diagnosis of the gastrointestinal disease; d) automatically selecting possible image features of an in vivo image from the registration bundle, associated with one pass, using algorithmic classification; e) retrieving a global index and an anatomical index and computing local travel distance based on said global

Art Unit: 2624

index and said anatomical index; and f) retrieving corresponding images in a neighborhood of said computed local travel distance from another pass based on prior selection of the possible image features (column 15, line 54 through column 16, line 7).

Claims 25-28 would be allowable if a terminal disclaimer is timely filed to overcome the obviousness-type double patenting.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-24, are rejected under 35 U.S.C. 103(a) as being unpatentable over Horn et al (U.S. patent 7,215,338) in view of Meron (U.S. patent 6,950,690).

Regarding claim 1, Horn discloses a system for identifying anatomical structure depicted in an in vivo image, comprising: a) an examination bundle that includes an in vivo image (see abstract, an in-vivo sensing system and a method for creating a summarized graphical presentation of a data stream captured in-vivo. The graphical presentation may be in the form of for example a color bar, as the data stream is displayed and/or streamed so as to indicate to a health professional what part of the data stream may be currently displayed. The color content in the color bar may map out the data stream and give indication of the location of anatomical sites as well as possible locations of pathology, also column 1, line 65 through column 2, line 7, the present invention may provide a system and method for generating and displaying a fixed graphical presentation of captured in-vivo data streams. In one embodiment of the present

Art Unit: 2624

invention, the fixed graphical presentation is a varying visual representation of a quantity or a dimension captured in an in-vivo data stream. In one example the graphical presentation is in the form of a color bar. In other embodiments of the present invention, the fixed graphical presentation may be displayed along side a streaming display of a data stream);

b) a gastrointestinal atlas that includes a list of individual anatomical structures and characterization data of the individual anatomical structures (column 3, lines 18-37, in one embodiment of the invention, the presentation may map out a varying quantity (e.g. a captured data stream) and may, for example, give indication of the relationship between the data stream captured and the anatomical origin or position relative to a start of the captured data stream, for example, the approximate or exact site, for example, in the GI tract from where various data captured may have originated. In another embodiment of the invention, the mapping may give, for example, an indication of an event (e.g. a physiological event) captured, measured, or otherwise obtained. In yet another embodiment of the invention, the mapping may give for example an indication of change of one or more parameters measured over time, for example, a change occurring due to pathology, a natural change in the local environment, or due to other relevant changes. The location may be relative to other information, for example, anatomical attributes along for example the GI tract. The location may in some embodiments be an absolute location, such as a location based on time or based on position of an in-vivo information capture device, based on an image frame in a sequence of images, also column 9, lines 33-42, international application published as WO02102223, entitled “MOTILITY ANALYSIS WITHIN A GASTROINTESTINAL TRACT” assigned to the assignee of the present invention and incorporated by reference herein in its entirety includes, inter alia, a device, system, and

Art Unit: 2624

methods for determining in-vivo motility that may be used in conjunction with the device, system, and method described herein).

However Horn discloses (column 7, line 52 through column 8, line 7, FIG. 4A shows a schematic example of a pH color bar 225 that may map out pH measurements obtained, for example over time or alternatively along a path of a body lumen. Other measurements may be used, for example, temperature, blood sensor, and pressure measurements may be used. Data obtained from an in-vivo pH sensor may be displayed with color, brightness, and/or patterns to map out the pH over time and/or over a path, for example a GI tract where different colors may represent, for example, different pH levels. In other examples, different colors may represent different levels of changes in pH levels. Other suitable presentations may be displayed.

Changes in pH along a path may be due to pathology, entrance into or out of anatomical locations, etc. Observed changes in pH over time may, for example, “classify” physiological occurrences over time, for example a healing process, progression of a medical condition, etc.

FIG. 4B is a schematic illustration of blood detecting color bar 226. In one example, color stripes 222 along the bar may indicate a site where blood may have been detected. But does not explicitly state its corresponding “the gastrointestinal atlas to identify the anatomical structure”.

On the other hand Meron in the same field of generating a map of the gastrointestinal tract teaches (see column 7, lines 14-24, recording a first set of images from a gastrointestinal tract using a swallowable imaging device; identifying an image showing a location of interest; recording a second set of images from the gastrointestinal tract using a swallowable imaging device; and performing image analysis by comparing images from the first set with images from the second set to identify in the second set an image of interest corresponding to an image in the

Art Unit: 2624

first set, thereby determining the location of the imaging device relative to the location of interest).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Horn invention according to the teaching of Meron because combination of Horn classify physiological occurrences over time and Meron performing image analysis by comparing images from the first set with images from the second set to identify in the second set an image of interest corresponding to an image in the first set, provides accurate diagnostic, which can easily be implemented in an imaging device.

Regarding claim 2, Horn discloses the system claimed in claim 1, wherein the classification engine includes a classifier identifying the anatomical structure depicted in the in vivo image (see claim 1, also column 7, lines 1-10, the present invention, the color scheme of image frames taken of tissue over time may change, for example as an in-vivo imaging device 40 travels along the GI tract. Changes in the color scheme of the images may be used to “identify”, for example, passage through a specific anatomical site, for example, the duodenal, cecum or other sites, and/or may indicate pathology, for example bleeding or other pathology).

Regarding claim 4, Horn discloses the system claimed in claim 1, wherein the classification engine uses image based classification methods for analyzing the examination bundle and the gastrointestinal atlas (see claim 1, also column 3, lines 1-17, system and method for generating a fixed graphical presentation of a captured data stream, for example image streams, other non-imaged data, or other data such as color coded, possibly imaged data (e.g. pH data, temperature data, etc.) that may have been collected in vivo, for example along the GI tract. The summarized graphical presentation may include, for example, a varying visual

Art Unit: 2624

representation, for example, a series of colors that may be at least partially representative of a quantity and/or data collected, e.g. a series of colors where each color presented on the bar may be representative of a value of a parameter. Other suitable representations may be used, and other visual dimensions or qualities, such as brightness, size, width, pattern, etc. may be used. In some embodiments of the present invention, the summarized graphical presentation may be a fixed display along side a streaming display of the data stream).

Regarding claim 5, Horn discloses the system claimed in claim 1, wherein the classification engine extracts image based features from the examination bundle for comparison with image specific characterization data in the gastrointestinal atlas (see claim 1, also column 10, lines 21-39, various suitable methods may be used to abstract data from the source data stream (e.g. an image stream, a series of temperature data) to the fixed representation. Reference is now made to FIG. 7 describing a method of generating a fixed summary of a data representation, for example a tissue color bar, according to an embodiment of the present invention. In an exemplary embodiment, in block 510 a set (wherein set may include one item) or series of data items, for example frames from an image stream may be extracted. For example every 10^{sup}.th frame from the image stream may be extracted and/or chosen to represent the image stream in a fixed presentation. In other embodiments, all the data items or frames may be included, or every 5^{sup}.th, 20^{sup}.th, or any other suitable number of frames may be used. In yet other embodiment of the present invention, an image representing an average of every two or more frames may be used. In one example, a criterion may be defined by which to define one frame out of a block of frames (e.g. two or more frames) to be representative of that block).

Art Unit: 2624

Regarding claim 7, Horn discloses the system claimed in claim 5, wherein the image specific characterization data is selected from the group consisting of representative images of the anatomical structure captured from various positions and orientations, from various illumination levels, color and/or texture distributions, and features of representative images of the anatomical structure (column 7, lines 1-40, the present invention, the color scheme of image frames taken of tissue over time may change, for example as an in-vivo imaging device 40 travels along the GI tract. Changes in the color scheme of the images may be used to identify, for example, passage through a specific anatomical site, for example, the duodenal, cecum or other sites, and/or may indicate pathology, for example bleeding or other pathology. When presenting an image stream of a tissue in a summarized, concise color bar, the changes in color streams may be readily identified. For example, passage into the cecum may be identified by a color that may be typical to the large intestine, for example, a color that may indicate content or a color typical of the tissue found in the large intestine. Entrance into the duodenum may be identified by another color that may be typical of the tissue in the small intestine. Other anatomical sites may be identified by observing color and/or changing color streams on a color bar, for example, a tissue color bar. In other embodiments a pathological condition, such as for example, the presence of polyps, bleeding, etc., may be identified by viewing, for example, a tissue graphical presentation 220. A specific area of interest, such as pathology indicated by blood, may be directly identified through the tissue. As such a health professional may first examine the tissue graphical presentation 220 and only afterwards decide what block of images to review. In some embodiments of the present invention, an algorithm may be employed to identify anatomical sites, pathologies, or areas of interest using data from such a color bar and

Art Unit: 2624

bring them to the attention of a health professional, by for example marking the area of interest along the displayed color bar).

Regarding claim 8, Horn discloses the system claimed in claim 6, wherein the non-image specific characterization data is selected from the group consisting of the average length or size of the anatomical structure, average relative position of the anatomical structure along the gastrointestinal tract and/or with respect to other anatomical structures, average pH, temperature, pressure levels of the anatomical structure, and average motility characteristics of the anatomical structure (column 9, line 43 through column 10, line 6, FIG. 6 showing a flow chart of a method for presentation of an in-vivo data stream according to an embodiment of the present invention. In block 610 a fixed presentation of a data stream may be displayed, e.g. a color bar, a series of strips of varying width or brightness, etc., summarizing, for example, an image stream, a PH data stream, temperature data stream etc. A user may annotate portions of the fixed presentation (block 680) for example identified anatomical sites and/or physiological events. More than one fixed presentation may be displayed. In block 620 a time bar indicating the time that data from a displayed data stream may have been sampled and/or captured may be displayed. A time bar need not be used. The data stream to be displayed may be initiated (block 630) so as, for example, to begin the streaming display. In block 640, streaming of the data stream may begin. The displayed data stream may be other than the data stream represented in the fixed presentation. For example, an in-vivo device may capture images as well as sample, for example, temperature values, as it progresses through the body lumen. In one example, a fixed presentation of temperature values may be displayed along side a streaming display of image frames captured substantially simultaneously. In other examples, the fixed presentation as well

Art Unit: 2624

as the streaming display may be of the captured image frame. In block 650 as the data stream progress, a cursor or other indicator may point to a position on the fixed presentation (as well as the time bar) that may correspond to the data (e.g., an image frame, a PH value) displayed in the displayed data stream. In block 660, a command may be received to stream the display from a different point in the data stream).

Regarding claim 9, Horn discloses the system claimed in claim 1, wherein the gastrointestinal atlas includes a list of anatomical structures selected from the group consisting of the mouth, pharynx, esophagus, cardiac orifice, stomach, pylorus, duodenum, jejunum, ileum, ileocecal valve, cecum, colon, rectum, and anus (column 7, lines 1-12, passage through a specific anatomical site, for example, the duodenal, cecum).

With regard to claims 3, 6 and 10-16 the arguments analogous to those presented above for claims 1, 2, 5, 7 and 8-9 are respectively applicable to claims 3, 6 and 10-16.

With regard to claims 17-24 the arguments analogous to those presented above for claims 1, 2, 4, 7 and 9 are respectively applicable to claims 17-24.

REASONS FOR ALLOWANCE

6. The following is an examiner's statement of reasons for allowance.

This invention relates generally, to an in vivo camera system and, in particular, to classifying images captured by an in vivo camera system according to anatomical structure.

With respect to claim 25, the closest prior art of record (Horn and Meron), Horn reference is directed to presentations of data streams and to a system and method for presenting in-vivo data, and Meron reference is directed to a method for identifying a target location in the gastrointestinal tract and for direct delivery of a device to the identified location. But neither Horn nor Meron teach or suggest, among other things, "constructing a selection set containing at

least one anatomical structure from the gastrointestinal atlas, associating with each anatomical structure in the selection set a capture rate, capturing in vivo images of an anatomy at a first capture rate to generate a series of image packets; e) generating an examination bundle for at least one of image packets, analyzing the examination bundle and the gastrointestinal atlas to identify the anatomical structure depicted in the in vivo image, "adjusting the first capture rate to an adjusted capture rate associated with identified anatomical structure upon identification of an anatomical structure belonging to the selection set".

These key features in combination with the other features of the claimed invention are neither taught nor suggested by (Horn and Meron) prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Seyed Azarian whose telephone number is (571) 272-7443. The examiner can normally be reached on Monday through Thursday from 6:00 a.m. to 7:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Bella, can be reached at (571) 272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR.

Art Unit: 2624

Status information about the PAIR system, see [http:// pair-direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Seyed Azarian/

Primary Examiner, Art Unit 2624

May 9, 2009